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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,034	09/05/2003	James Hunter Boone	TLAB.100294	8482

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,034	BOONE ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 24, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 17-24* is/are pending in the application.

4a) Of the above claim(s) *4,5 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-14,17,18 and 20-24* is/are rejected.

7)☒ Claim(s) *2 and 3* is/are objected to.

8)☒ Claim(s) *1-14 and 17-24* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicants' reply, filed May 24, 2006, which amended claims 1-3, 8, 11, 12, 17 and 22.

Claims 4-5 and 19 remain withdrawn from further consideration pursuant to 37 CFR 1 .142(b) as being drawn to nonelected species.

Currently, claims 1-3, 6-14, 17, 18 and 20-24 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The disclosure is objected to because of the following informalities:

The information presented in Table 1 does not correspond to information presented in Table 2. Specifically, Table 1 references 203 patients (*i.e.*, 98 IBD patients + 47 patients with Crohn's disease + 51 patients with ulcerative colitis + 7 patients with irritable bowel syndrome) and 11 healthy persons, while Table 2 references 32 patients (*i.e.*, 21 ANCA + UC, 4 ANCA +CD, and 7 IBS) and 11 healthy persons. The disappearance of 171 patients from Table 2 is not clear.

The information presented in Table 1 does not correspond to information presented in Table 3. Specifically, Table 1 references a total of 214 persons (*i.e.*, 203 patients + 11 healthy persons), while Table 3 references a total of 116 persons (*i.e.*, Total Assessments N = 116). The disappearance of 98 persons from Table 3 is not clear.

The information presented in Table 2 does not correspond to information presented in Table 3. Specifically, Table 2 references a total of 43 persons (*i.e.*, 32 patients + 11 healthy persons), while Table 3 references a total of 116 persons (*i.e.*, Total Assessments N = 116). The addition of 73 persons into Table 3 is not clear.

In Table 3, the value for Total Assessments N = 116 does not correspond to the number of persons listed in Table 3 (*i.e.*, 98 IBD patients + 47 patients with Crohn's disease + 51 patients with ulcerative colitis + 7 patients with irritable bowel syndrome + 11 healthy persons).

Appropriate correction is required.

Claim Objections

Claims 2-3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the language recited in claims 2-3 do not appear relevant to a method of "testing a fecal sample" as recited in the preamble of claim 1. How the language recited in claims 2-3 further limits a method of "testing a fecal sample" is not clear.

Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 USC § 112 – second paragraph

Claims 2-3, 8-13, 17-18 and 20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2, 12 and 17, the passive voice recitation "is concluded" is indefinite because the identity of object(s) and/or step(s), if any, required for performing conclusion, or achieving a state of conclusion, is/are not clear.

In claims 2-3, the recited steps do not appear relevant to a method of "testing a fecal sample" as recited in the preamble of claim 1. How the language recited in claims 2-3 further limits a method of "testing a fecal sample" is not clear.

In claims 3 and 18, the passive voice recitation "is used" is indefinite because the identity of object(s) and/or step(s), if any, required for performing "using" is not clear.

In claims 3 and 18, the infinitive "to aid" is indefinite. Whether the act or process of "aiding" is completed, performed, or merely intended is not clear. The identity of object(s) and/or step(s), if any, required for performing "aiding" is not clear.

In claims 6 and 20, the recitation of "total anti-neutrophil cytoplasmic antibodies" is indefinite. Whether/how the noun "antibodies" is modified by the adjective "total" is not clear.

In claim 11, the claim preamble does not correspond to the method outcome. For example, the preamble recites a "diagnostic assay", while the final step requires "determining the optical density of the readable

sample". Whether/how "determining the optical density of the readable sample" amounts to a "diagnostic assay" is not clear.

In claim 14, the phrase "[t]he diagnostic assay as recited in claim 1" lacks antecedent basis in claim 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6-14, 17, 18 and 20-24 are rejected under 35 U.S.C. 101 because the claimed invention lacks credible utility.

Independent claim 1 recites a method for "testing a fecal sample" for anti-neutrophil cytoplasmic antibodies (hereinafter "ANCA"). Independent claim 11 recites a "diagnositic assay for ulcerative colitis". Independent claim 17 recites a method for "screening for ulcerative colitis".

Applicants' specification posits that testing fecal samples for ANCA is specifically useful for "an indicator of ulcerative colitis", "differentiating between ulcerative colitis and Crohn's disease (see Specification, paragraph [0014], first sentence), and "differentially diagnosing ulcerative colitis from... Irritable Bowel Syndrome" (see Specification, paragraph [0009]).

Applicants' assertion of utility is based on data obtained from a clinical study involving patients presenting with "Crohn's Disease" and "ulcerative colitis"[1] and/or "irritable bowel syndrome"[2] (see Specification, paragraph [0017] *et seq.*). In the clinical study, Applicants used standard immunoassay techniques to determine whether fecal samples from patients possessed ANCA.

According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic

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[1] Crohn's Disease and ulcerative colitis belong to a disease class called Inflammatory Bowel Diseases (IBD). See MeSH Database, Inflammatory Bowel Diseases, *available at* <http://www.ncbi.nlm.gov>.

underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicants' assertion of specific utility is not credible because, according to Table 4 of Applicant's specification, only 41% of patients presenting with ulcerative colitis possessed ANCA (*i.e.*, ANCA is a useful indicator of ulcerative colitis in only 41% of patients). Therefore, based on the data in Table 4, it appears that ANCA is not specifically useful as "an indicator of ulcerative colitis". Necessarily, ANCA is not specifically useful for "differentiating between ulcerative colitis and Crohn's disease or "differentially diagnosing ulcerative colitis from... Irritable Bowel Syndrome".

Claim Rejections - 35 USC § 112 – first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-14, 17, 18 and 20-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a credibly-asserted utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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[2] Applicants' specification does not disclose what standard, if any, Applicants used to identify and include a patient as having "irritable bowel syndrome" into the clinical study.

Response to Arguments

Claim Rejections - 35 USC § 112 – second paragraph

In prior Office Action, claims 6 and 20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the phrase "total anti-neutrophil cytoplasmic antibodies" is considered unclear. Whether/how the noun "antibodies" is modified by the adjective "total" is not clear.

In response, Applicants disclose that "total anti-neutrophil cytoplasmic antibodies" references, *inter alia*, "degraded" and/or protease- and/or acid-digested forms of "anti-neutrophil cytoplasmic antibodies".

Applicants' argument is not sufficient to overcome this rejection. Claims 6 and 20 do not mention anything of "degraded" and/or protease- and/or acid-digested forms of "anti-neutrophil cytoplasmic antibodies". Examiner posits that persons skilled in the art may not be so imaginative as to import the clarifying details of Applicants' remarks into the plain meaning of either claims 6 or 20 to arrive at the notion of "total anti-neutrophil cytoplasmic antibodies" referencing "degraded" and/or protease- and/or acid-digested forms of "anti-neutrophil cytoplasmic antibodies".

Claim Rejections - 35 USC § 102

In prior Office Action, claims 1-3, 6-7, 14, 17-18 and 20-21 were rejected under 35 U.S.C. 102(e) as being anticipated by Fine (US 6,667,160).

In response, Applicants posit that "[a]ntitissue transglutaminase antibodies are different from anti-neutrophil cytoplasmic antibodies" (see Applicants' reply, sentence bridging pp. 11-12). Applicants provide no evidence in support of their position.

During a telephone interview with Applicants' representative on February 23, 2006, it was principally determined that antitissue transglutaminase antibodies are different from anti-neutrophil cytoplasmic antibodies. Accordingly, this rejection is withdrawn.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
Art Unit 1641

djv

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